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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,387	03/14/2001	Kaia Palm	CEMRES.001 A	3322
32940	7590	06/30/2004	EXAMINER	
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 4 EMBARCADERO CENTER SUITE 3400 SAN FRANCISCO, CA 94111			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/808,387

Applicant(s)

PALM ET AL.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 9-33 is/are pending in the application.
- 4a) Of the above claim(s) 2,11-20 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-6 and 21-29 is/are allowed.
- 6) ☒ Claim(s) 7,9,10 and 31 is/are rejected.
- 7) ☒ Claim(s) 31-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Status of the claims*

Claims 1-2, 4-7 and 9-33 are pending.

Applicants' amendment filed 4 June 2004, which cancels claims 3 and 8, amends claims 1, 4-7 and 24-29, and adds claims 31-33, and applicants' request (filed 4 June 2004) for extension of time of one month have been entered. The response filed 5 April 2004, which amends claim 32 has been entered. Note that claims 2, 11-20 and 30 are withdrawn from consideration by Examiner (see the Office action mailed 29 January 2004). Thus, claims 1, 4-7, 9-10, 21-29 and 31-33 together with the elected SEQ ID NO:21 are examined in this Office action.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

### *Claim Objection*

The disclosure is objected to because of the following informalities:

(1) In claim 31, 32 and 33, "SEQ ID NO:" should be changed to "SEQ ID NOs:".

Appropriate correction is required.

*The following is a new ground of rejection*

### *Claim Rejections - 35 USC § 112, the first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1653

Claims 7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe any subsequence (fragment) or variant of the full-length SEQ ID NO: 21 (*elected*) which hybridizes to said full-length nucleotide sequence. Thus, applicants are not in possession of isolated polynucleotide, which hybridizes under the recited condition in the claims, to the above-mentioned SEQ ID NO:21 sequence. The current claim language appears to encompass a large number of the polynucleotide variants including genetic and recombinantly produced mutations.

Applicants have disclosed only the polynucleotide of SEQ ID NO: 21; therefore, the skilled artisan cannot envision all the contemplated peptide sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993).

One of skill in the art would reasonably conclude that the disclosure fails to describes biological activity of the claimed polynucleotide and provide a representative number of the nucleotide subsequences or variants thereof to describe its use in the claims. Thus, Applicant was not in possession of the claimed polynucleotide variant. See *University of California v. Eli Lilly and co.* 43 USPQ2d 1398.

Art Unit: 1653

The Guidelines for the Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, *i.e.*, structure or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the applicants were in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

***Claim Rejections - 35 USC § 112, the second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the term "homology"; the term is not apparent because the term "homology" in molecular biology refers to having a common ancestor and homology cannot be measured (see the *attachment 1*). Suggest "sequence identity" instead.

Art Unit: 1653

***Conclusion***

Claims 7, 9-10 and 31-33 claims are not allowed; claims 1, 4-6 and 21-29 are free from the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

*SWL*

Samuel Wei Liu, Ph.D.

June 23, 2004

*Karen Cochrane Carlson PhD*

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER